

DETAILED ACTION

1. Claims 1, 6, 7, 9, 10, 13, and 20-29 are all the pending claims for this application.
2. Claim 18 was cancelled in the Response of 9/30/09.
3. Claims 1, 6, 7, 9, 10, 13, and 20-29 are all the pending claims in this application.
4. This Office Action is final.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

5. The rejection of Claims 1, 6, 7, 9, 10, 13 and 20-29 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The rejection was set forth in the Office Action of 6/30/09 as follows:

"Claim 1 and the dependent claims thereof are interpreted as being drawn to a composition comprising "one or more peptides" originating from any source or any kind of protein so long as the peptide(s) is eight to thirteen residues in length. Additionally, at least one of the peptides in the composition is the CTL epitope of SEQ ID NO: 53, 55, 139, 502, 527, 627, 673, 807, 846, 859 or admixtures thereof. Thus, with the exception of the peptides of SEQ ID NO: 53, 55, 139, 502, 527, 627, 673, 807, 846, 859 or admixtures thereof, the remaining genus of peptides falling within the scope of composition Claim 1 is unlimited in both structure and function. This is a reach-through claim for the genus of all peptides having the only requirement that it is eight to thirteen residues in length. The genus of peptides does not find written support in the specification and prior art.

Claim 18 requires that the peptides comprising the composition of Claim 1 would be useful as a diagnostic reagent, and the specification does not support the genus of peptides meeting this criterion.

Under the Written Description Guidelines (66 FR 1099 (Jan. 5, 2001); 1242 O.G. 168 (Jan. 30, 2001) revised training materials 3/29/08), the claimed invention must meet the following criteria as set forth.

a) Actual reduction to practice: The specification discloses compositions comprising immunogenic peptides [0008; 0087; 0090; 0092], and having binding motifs specific for MHC molecules [0008]. The at least one of the one or more peptides is a peptide from an antigen selected from the group consisting of prostate specific antigen (PSA), prostate specific membrane antigen (PSM), hepatitis B virus (HBV) antigen, hepatitis C virus (HCV) antigen, malignant melanoma antigen (MAGE), Epstein Barr virus, human immunodeficiency type-1 (HIV-1), human immunodeficiency type-2 (HIV-2), papilloma virus, Lassa virus, mycobacterium tuberculosis (MT), p53, murine p53 (mp53), CEA, HER2/neu, and tyrosine kinase related protein (TKP) (Claim 13 in the PGPub). Tables 11-29 define:

HLA-A1 allele-binding peptides (Table 11); HLA-A2 allele-binding peptides (Table 13); HLA-A3 allele-binding peptides (Table 15); HLA-A24 allele-binding peptides (Table 17); HLA-B7 allele-binding peptides (Table 19); HLA-B44 allele-binding peptides (Table 21); HLA-DQ allele-binding peptides (Table 23); HLA-DR allele-binding peptides (Table 25); and murine MHC class I allele-binding peptides (Table 28) and their respective binding affinities.

The specification does not support compositions comprising just any peptide of eight to thirteen residues in length from just any protein. The peptides of the invention are at a minimum immunogenic and are more specifically MHC binding.

b) Disclosure of drawings or structural chemical formulas: the specification and drawings do not show that applicant was in possession of the genus of just any peptide of eight to thirteen residues in length from just any protein that is included in the composition.

c) Sufficient relevant identifying characteristics: the specification does not identify 1) a complete structure, ii) partial structure, iii) physical and/or chemical properties, or iv) functional characteristics coupled with correlation between structure and function for the genus of just any peptide of eight to thirteen residues in length from just any protein that is included in the composition.

d) Method of making the claimed invention: the specification teaches methods for identifying immunogenic, MHC (HLA)-binding epitopes from immunogenic proteins in the form of peptides that range in size from eight to thirteen residues.

e) Level of skill and knowledge in the art: the screening of proteins for immunogenic epitopes having MHC binding activity and CTL activity was well established at the time of the invention.

f) Predictability in the Art: it is predictable that Applicants could generate any peptide that ranges in size from eight to thirteen residues. It is unpredictable that just any one of the peptides would have a structure that conferred some property much less a property relevant to binding MHC (HLA) or being a CTL epitope absent a structure function correlation for the peptide. It is unpredictable that just any peptide would have a diagnostic function as a component in a diagnostic composition (See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."); "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)).

Scholnick et al (Trends in Biotechnology, 18(1):34-39, 2000, cited in the PTO 892 form of 1/14/08) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based on sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to function of the structurally related protein (see in particular "Abstract" and Box 2).

Applicants have not demonstrated with sufficient evidence the genus of just any peptide of eight to thirteen residues in length from just any protein that is included in the composition much less where the peptide is a diagnostic peptide comprised in a diagnostic composition."

Applicants allegations on pp. 6-8 of the Response of 9/30/09 have been considered and are not found persuasive. Applicants allege that in amending Claim 1 to recite that from within the composition a peptide comprising a CTL epitope being selected from the group consisting of SEQ ID NOs: 527, 673, 846, 627, 139, 859, 502, 53, 55, 807, and admixtures thereof, the compositions are now drawn to only those species of peptides in the Markush group.

Response to Arguments

It is correct that the claims recite that the composition would comprise at least one of the CTL peptides of the Markush group. However, it is incorrect that other myriad peptides having no known structure or no known function but being of any eight to thirteen residues in length, could also be present along with the recited CTL peptides. MPEP 2111.02 states in part:

"The transitional term 'comprising', which is synonymous with 'including,' 'containing,' or 'characterized by,' is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ('like the term comprising,' the terms containing' and mixture' are open-ended.').< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ('The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.');

Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ('Comprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). >In Gillette Co. v. Energizer Holdings Inc., 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to 'a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades' encompasses razors with more than three blades because the transitional phrase 'comprising' in the preamble and the phrase 'group of' are presumptively open-ended. 'The word comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended."

Id. In contrast, the court noted the phrase "group consisting of" is a closed term, which is

often used in claim drafting to signal a "Markush group" that is by its nature closed. *Id.* The court also emphasized that reference to "first," "second," and "third" blades in the claim was not used to show a serial or numerical limitation but instead was used to distinguish or identify the various members of the group. *Id.*<"

The rejection is maintained.

Conclusion

6. No claims are allowed.
7. The closest reference art found to read on the CTL epitope of SEQ ID NO: 53, 55, 139, 502, 527, 627, 673, 807, 846, or 859 is Grey et al. (10/817,970 (priority to 4/6/04)) and Baker et al. (11/027,670 (filed 1/3/05)). The references are not effective prior art as Applicants' priority for the sequences to U.S. Provisional Application No. 60/416,207 (filed 10/3/02) antedates the references.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/
Primary Examiner, Art Unit 1643